

# Malignant transformation and tumour recurrence in sacrococcygeal teratoma, a congenital disorder in newborns

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<b>Registration date</b> 28/04/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/11/2024	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Sacrococcygeal teratoma (SCT) is a rare congenital disorder with an estimated incidence of 1:15,000 to 1:30,000. The treatment is complete resection, but in a substantial proportion of patients, the tumour recurs, often as malignancy. There is scant data on the true recurrence rate of SCT, the timing of recurrence, how recurrence is diagnosed and risk factors for recurrence including histology of the primary tumour. This study aims to assess the SCT recurrence rate, the time after which SCT recurrence occurs, pathology, whether recurrence is a primary or recurrent tumour, and how recurrent SCT is diagnosed.

### Who can participate?

All patients with SCT treated by each participating centre during a set period of time will be included. Patients with Currarino triad-associated SCT (arising from defects that occur during embryonic development) are specifically included.

### What does the study involve?

Participating centers confirm their participation, the inclusion of consecutive patients in a set period of time and sign a data transfer agreement form which defines data ownership, data use, protection and storage of data and authorship.

### What are the possible benefits and risks of participating?

There is no benefit for the individual included patient in this study. However, The United Nations encourages nations to create networks of experts for rare diseases and to increase research support, by strengthening international collaboration and coordination of research efforts and the sharing of data, while respecting its protection and privacy. This collaborative study enables the identification of risk factors for recurrent SCT and essential information regarding malignant SCT transformation. With large, shared patient data sets, it is possible to answer important clinical questions that cannot be answered otherwise to improve the quality of care in every part of the world.

Due to the design of the study including only retrospective patient data, there are no risks for individual patients.

Where is the study run from?

Amsterdam University Medical Centre in the Netherlands

When is the study starting and how long is it expected to run for?

December 2020 to January 2022

Who is funding the study?

KiKa Children's Cancer Free Foundation

Who is the main contact?

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

KiKa project 440

## Study information

### Scientific Title

Malignant transformation and tumour recurrence in patients with SacroCoccygeal Teratoma: a global, retrospective cohort study

### Acronym

SCT-study

### Study objectives

Sacrococcygeal teratoma (SCT) is a rare congenital disorder with an estimated incidence of 1:15,000 to 1:30,000. The treatment is complete resection, but in a substantial proportion of patients, the tumour recurs, often as malignancy. There is limited data on the true recurrence rate of SCT, the timing of recurrence, how recurrence is diagnosed and risk factors for recurrence including histology of the primary tumour.

### Ethics approval required

Ethics approval not required

### Ethics approval(s)

The Medical Ethical Board of Amsterdam University Medical Centre (Amsterdam UMC), determined that the Medical Research Involving Human Subject Act (WMO) does not apply to the study and that official approval of the committee was not required (reference number W19\_329 # 19.388).

### Study design

Multicentre observational retrospective cohort study

### Primary study design

Observational

**Study type(s)**

Diagnostic, Treatment

**Health condition(s) or problem(s) studied**

Sacrococcygeal teratoma

**Interventions**

This observational study looks at tumour histology at initial resection and the time between birth and surgery. Furthermore, risk factors associated with recurrence will be analysed.

Collected data included generic and condition-specific variables. Generic variables included: country, gender (male/female/unknown), age at diagnosis (days), pre-operative imaging modalities (none/ultrasound/computed tomography/magnetic resonance imaging/unknown), initial tumour resection at the participating centre (yes/no/unknown), age at initial resection (days), outcome (survival/deceased/unknown), age at follow-up (days), age at death (days), and cause of death. Condition-specific variables were Altman classification (I/II/III/IV/unknown), CS (yes/no/unknown), initial SCT treatment (chemotherapy/surgery/no treatment/unknown), pathology (mature/immature/malignant/unknown), recurrence (yes/no/unknown), the period between birth and recurrence (days), detection of recurrence (clinical examination/imaging/AFP/unknown), serum AFP-level at recurrence ( $\mu\text{g/L}$ ), recurrent SCT pathology (mature/immature/malignant/unknown) and treatment of recurrent SCT (chemotherapy/surgery/no treatment/unknown). These data were used to calculate the risk of malignant transformation and risk factors associated with sacrococcygeal teratoma recurrence.

**Intervention Type**

Procedure/Surgery

**Primary outcome(s)**

The following primary outcomes are measured using patient medical records at a one-time point:

1. Malignant transformation of the initial tumour confirmed by pathology.
2. Risk factors associated with sacrococcygeal teratoma recurrence defined as relapse of the tumour at least three months after initial resection.

**Key secondary outcome(s)**

The following secondary outcomes are measured using patient medical records at a one-time point:

1. Treatment modality for sacrococcygeal teratoma patients from different income countries
2. Outcomes of treatment for sacrococcygeal teratoma patients from different income countries

**Completion date**

01/01/2022

**Eligibility****Key inclusion criteria**

All patients with SCT treated by each participating centre during a set time

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

All

**Sex**

All

**Total final enrolment**

3612

**Key exclusion criteria**

Patients treated for sacrococcygeal teratoma before 1980

**Date of first enrolment**

01/12/2020

**Date of final enrolment**

01/01/2022

**Locations****Countries of recruitment**

United Kingdom

Afghanistan

Argentina

Austria

Bangladesh

Belarus

Belgium

Brazil

Bulgaria

Cameroon

Canada

Chile

China

Croatia

Czech Republic

Côte d'Ivoire

Denmark

Egypt

Estonia

Ethiopia

Finland

France

Germany

Ghana

Greece

Hong Kong

Hungary

India

Indonesia

Iran

Iraq

Ireland

Israel

Italy

Japan

Korea, South

Latvia

Lithuania

Malaysia

Mexico

Montenegro  
Morocco  
Netherlands  
Nigeria  
North Macedonia  
Norway  
Pakistan  
Philippines  
Poland  
Portugal  
Romania  
Russian Federation  
Serbia  
Singapore  
Slovakia  
Slovenia  
Spain  
Sri Lanka  
Sweden  
Syria  
Taiwan  
Thailand  
Tunisia  
Türkiye  
Ukraine  
United States of America

Zambia

**Study participating centre**  
**Hospital Garrahan Buenos Aires**  
Argentina

-

**Study participating centre**  
**Hospital Italiano de Buenos Aires**  
Argentina

-

**Study participating centre**  
**Medical University of Graz**  
Austria

-

**Study participating centre**  
**Bangladesh Shishu Hospital & Institute**  
Bangladesh

-

**Study participating centre**  
**Center of Pediatric Surgery of Belarusb**  
Belarus

-

**Study participating centre**  
**Universitair Ziekenhuis Brussel**  
Belgium

-

**Study participating centre**  
**Hôpital des Enfants Reine Fabiola, Université Libre de Bruxelles**  
Belgium

-

**Study participating centre**  
**Federal University of São Paulo**  
Brazil

-

**Study participating centre**  
**University Hospital "St. George"**  
Bulgaria

-

**Study participating centre**  
**UMHATEM "N. I. Pirogov" Sofia**  
Bulgaria

-

**Study participating centre**  
**Yaounde Gynaeco-Obstetric and Pediatric Hospital-faculty of medicine**  
Cameroon

-

**Study participating centre**  
**McGill University, Montreal Children's Hospital**  
Canada

-

**Study participating centre**  
**Shriners Hospital for Children**  
Canada

-

**Study participating centre**  
**The Hospital for Sick Children**  
Canada

-

**Study participating centre**  
**Hospital de Niños Dr. Roberto del Rio**  
Chile  
-

**Study participating centre**  
**Guangzhou Women and Children's Medical Center**  
China  
510623

**Study participating centre**  
**University Hospital centre Zagreb**  
Croatia  
-

**Study participating centre**  
**University Hospital of Split and Department of Surgery, University of Split**  
Croatia  
-

**Study participating centre**  
**Charles University and University Hospital Motol**  
Czech Republic  
150 06

**Study participating centre**  
**Rigshospitalet Copenhagen University Hospital**  
Denmark  
-

**Study participating centre**  
**Ain Shams University**  
Egypt  
-

**Study participating centre**

**Kasr Al Ainy Faculty of Medicine**  
Egypt

-

**Study participating centre**  
**Pediatric Surgery Cairo University**  
Egypt

-

**Study participating centre**  
**Tallinn Children's Hospital**  
Estonia

-

**Study participating centre**  
**St.Peter Specialized Hospital**  
Ethiopia

-

**Study participating centre**  
**New Children´s Hospital**  
Finland

-

**Study participating centre**  
**Hôpital des Enfants de Toulouse**  
France

-

**Study participating centre**  
**CHU Rennes, Univ Rennes**  
France

-

**Study participating centre**

**Limoges University Hospital Center**

France

-

**Study participating centre**

**University Hospital Angers**

Angers

France

-

**Study participating centre**

**Hospital for sick children La Timone, Assistance publique des hôpitaux de Marseille**

Marseille

France

-

**Study participating centre**

**orbonne Université, Armand Trousseau Hospital –Assistance Publique Hôpitaux de Paris,**

Paris

France

-

**Study participating centre**

**Hopitaux Pédiatriques de Nice CHU-Lenval**

Nice

France

-

**Study participating centre**

**University Hospital, Poitiers**

Poitiers

France

-

**Study participating centre**

**Hôpital Necker-Enfants Malades - APHP GH Centre and Université de Paris Cité**

Paris

France

-

**Study participating centre**  
**University Hospital of Lille Jeanne de Flandre**  
Lille  
France

-

**Study participating centre**  
**Dr. von Hauner Children's Hospital, University Hospital**  
Munich  
Germany

-

**Study participating centre**  
**University Medical Center Mannheim, Heidelberg University**  
Mannheim  
Germany

-

**Study participating centre**  
**University of Leipzig**  
Leipzig  
Germany

-

**Study participating centre**  
**Charité Universitätsmedizin Berlin, corporate member of Freie Universität Berlin and Humboldt  
Universität zu Berlin**  
Berlin  
Germany

-

**Study participating centre**  
**University Hospital Frankfurt/M.**  
Frankfurt  
Germany

-

**Study participating centre**  
**Accra College of Medicine**  
Accra  
Ghana

-

**Study participating centre**  
**P. & A. Kyriakou Children's Hospital**  
Athens  
Greece

-

**Study participating centre**  
**Semmelweis University**  
Budapest  
Hungary

-

**Study participating centre**  
**Medical School, University of Pécs**  
Pécs  
Hungary

-

**Study participating centre**  
**Li Ka Shing Faculty of Medicine, University of Hong Kong**  
Hong Kong

-

**Study participating centre**  
**Amrita Institute Of medical sciences**  
Kerala  
India

-

**Study participating centre**  
**All India Institute of Medical Sciences**  
Jodhpur

India

-

**Study participating centre**

**All India Institute of Medical Sciences**

New Dehli

India

-

**Study participating centre**

**Faculty of Medicine, Public Health and Nursing, Universitas Gadjah Mada, Dr. Sardjito Hospital**

Yogyakarta

Indonesia

-

**Study participating centre**

**Research Institute for Children's Health, Shahid Beheshti University of Medical Sciences**

Teheran

Iran

-

**Study participating centre**

**Alkhansaa teaching hospital**

Mosul

Iraq

-

**Study participating centre**

**Children's Health Ireland at Crumlin**

Dublin

Ireland

-

**Study participating centre**

**Tel Aviv Sourasky Medical Center**

Tel Aviv

Israel

-

**Study participating centre**  
**IRCCS Istituto Giannina Gaslini**  
Genoa  
Italy  
-

**Study participating centre**  
**Children's Hospital Bambino Gesù-Research Institute**  
Rome  
Italy  
-

**Study participating centre**  
**University of Padua**  
Padua  
Italy  
-

**Study participating centre**  
**Regina Margherita Children's Hospital**  
Turin  
Italy  
-

**Study participating centre**  
**Bambino Gesù' Pediatric Hospital**  
Rome  
Italy  
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**Study participating centre**  
**Sant'Orsola Hospital, IRCSS, University of Bologna**  
Bologna  
Italy  
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**Study participating centre**

**Meyer Children's Hospital IRCCS Florence**

Florence

Italy

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**Study participating centre**

**Fondazione IRCCS Policlinico San Matteo**

Pavia

Italy

-

**Study participating centre**

**Cocody Teaching Hospital at Abidjan**

Abidjan

Côte d'Ivoire

-

**Study participating centre**

**Kyoto Prefectural University of Medicine**

Kyoto

Japan

-

**Study participating centre**

**Saitama Children's Medical Center**

Saitama

Japan

-

**Study participating centre**

**National Center for Child Health and Development**

Tokyo

Japan

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**Study participating centre**

**Graduate School of Medical Sciences, Kyushu University**

Fukuoka

Japan

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**Study participating centre**

**Osaka City General Hospital**

Osaka

Japan

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**Study participating centre**

**Graduate School of Medical Sciences, Kyushu University,**

Fukuoka

Japan

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**Study participating centre**

**Tokyo Metropolitan Children's Medical Center**

Tokyo

Japan

-

**Study participating centre**

**Riga Stradins University & Children's Clinical University Hospital**

Riga

Latvia

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**Study participating centre**  
**Faculty of Medicine, Universiti Kebangsaan Malaysia**  
Kuala Lumpur  
Malaysia

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**Study participating centre**  
**Hospital Tunku Azizah, Kuala Lumpur Women's and Children's Hospital**  
Kuala Lumpur  
Malaysia

-

**Study participating centre**  
**Instituto Nacional de Pediatría**  
Mexico City  
Mexico

-

**Study participating centre**  
**Institute for children's diseases, Clinical Centre of Montenegro**  
Podgorica  
Montenegro

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**Study participating centre**  
**University hospital Mohamed VI, Cadi Ayyad University,**  
Marrakesh  
Morocco

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**Study participating centre**

**University Medical Center Groningen**

Groningen  
Netherlands

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**Study participating centre**

**Radboud University Medical Center, Amalia Children's Hospital**

Nijmegen  
Netherlands

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**Study participating centre**

**Emma Children's Hospital, Amsterdam UMC, location University of Amsterdam,**

Amsterdam  
Netherlands

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**Study participating centre**

**University Medical Centre Maastricht**

Maastricht  
Netherlands

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**Study participating centre**

**Erasmus MC Sophia Children's Hospital**

Rotterdam  
Netherlands

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**Amsterdam Public Health Research Institute, Amsterdam UMC, Vrije Universiteit Amsterdam**

Amsterdam  
Netherlands  
1081 HV

**Study participating centre**

**University of Utrecht, Wilhelmina Children's Hospital, UMC Utrecht**  
Utrecht  
Netherlands  
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**Study participating centre**  
**Lagos University Teaching Hospital**  
Lagos  
Nigeria  
-

**Study participating centre**  
**Jos University Teaching Hospital**  
Jos  
Nigeria  
PMB 2076

**Study participating centre**  
**Nnamdi Azikiwe University Teaching Hospital**  
Nnewi  
Nigeria  
-

**Study participating centre**  
**Abubakar Tafawa Balewa University Teaching Hospital**  
Bauchi  
Nigeria  
-

**Study participating centre**  
**Oslo University Hospital**  
Oslo  
Norway  
4950

**Study participating centre**

**Liaquat National Hospital and Aga Khan university**

Karachi  
Pakistan

-

**Study participating centre**

**Children Hospital, Shaheed Zulfiqar Ali Bhutto Medical University**

Islamabad  
Pakistan

-

**Study participating centre**

**University of Child Health Sciences**

Lahore  
Pakistan

-

**Study participating centre**

**Philippine Children's Medical Center**

Quezon City  
Philippines

-

**Study participating centre**

**Philippine General Hospital**

Manila  
Philippines

-

**Study participating centre**

**The Children's Memorial Health Institute**

Warsaw  
Poland

-

**Study participating centre**

**Medical University of Gdansk**

Gdansk

Poland

-

**Study participating centre**

**Hospital Dona Estefania**

Lisboa

Portugal

-

**Study participating centre**

**Hospital Dona Estefânia**

Lisboa

Portugal

-

**Study participating centre**

**"Victor Babes" University of Medicine and Pharmacy Timisoara**

Timisoara

Romania

-

**Study participating centre**

**FSAI "NMRC of Children Health" MHRF**

Moscow

Russian Federation

-

**Study participating centre**

**Volgograd State Medical University**

Volgograd

Russian Federation

-

**Study participating centre**

**Irkutsk Regional Children's Hospital**

Irkutsk

Russian Federation

-

**Study participating centre**

**Stavropol State Medical University**

Stavropol

Russian Federation

-

**Study participating centre**

**Institute for Mother and Child Healthcare of Serbia "Dr Vukan Cupic"**

Belgrade

Serbia

-

**Study participating centre**

**University Children's Hospital, Center for Pediatric Surgery and Medical Faculty University of**

**Belgrade**

Belgrade

Serbia

-

**Study participating centre**

**KK Women's and Children's Hospital**

Singapore

-

**Study participating centre**

**National Institute of Children's Diseases**

Bratislava

Slovakia

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**Study participating centre**

**University Medical centre Ljubljana**

Ljubljana

Slovenia

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**Study participating centre**

**Seoul National University Hospital**

Seoul

Korea, South

03080

**Study participating centre**

**Asan Medical Center**

Seoul

Korea, South

-

**Study participating centre**

**Inje University Busan Paik hospital**

Busan

Korea, South

-

**Study participating centre**

**University Hospital Vall d'Hebron**

Barcelona

Spain

-

**Study participating centre**

**Children's Hospital La Paz**

La Paz

Spain

-

**Study participating centre**

**Virgen del Rocio Children's Hospital**

Sevilla

Spain

-

**Study participating centre**

**Hospital Universitario Reina Sofia**

Córdoba

Spain

-

**Study participating centre**

**Virgen de la Arrixaca University Clinical Hospital**

Murcia

Spain

-

**Study participating centre**

**La Fe University and Polytechnic Hospital**

Valencia

Spain

-

**Study participating centre**

**Lady Ridgeway Hospital**

Colombo

Sri Lanka

-

**Study participating centre**

**Skane University Hospital Lund**

Lund

Sweden

-

**Study participating centre**

**Karolinska University Hospital**

Stockholm

Sweden

-

**Study participating centre**

**Astrid Lindgren's Childrens Hospital**

Stockholm

Sweden

-

**Study participating centre**

**Children Hospital**

Damascus

Syria

-

**Study participating centre**

**Chang Gung University College of Medicine**

Taoyuan

Taiwan

-

**Study participating centre**

**Queen Sirikit National Institute of Child Health**

Bangkok

Thailand

-

**Study participating centre**

**Hedi Chaker Hospital University of medecine of Sfax**

Sfax

Tunisia

-

**Study participating centre**

**Fattouma Bourguiba Hospital**

Monastir

Tunisia

-

**Study participating centre**

**Ege University**

Izmir

Türkiye

-

**Study participating centre**

**Istanbul Medeniyet University Faculty of Medicine)**

Istanbul

Türkiye

-

**Study participating centre**

**Dr Sami Ulus Maternity and Children Health and Research Application Center**

Ankara

Türkiye

-

**Study participating centre**

**Faculty of Medicine & Cancer Institute Ankara**

Ankara

Türkiye

-

**Study participating centre**

**Hacettepe University, Faculty of Medicine**

Ankara

Türkiye

-

**Study participating centre**

**National Specialized Children Hospital "Ohmatdyt"**

Kyiv

Ukraine

-

**Study participating centre**

**Leeds Teaching Hospitals**

Leeds

United Kingdom

-

**Study participating centre**

**Cambridge University Hospitals NHS Foundation Trust**

Cambridge

United Kingdom

-

**Study participating centre**

**Great North Children's Hospital**

Newcastle

United Kingdom

-

**Study participating centre**

**Birmingham Children hospital UK**

Birmingham

United Kingdom

-

**Study participating centre**

**Royal Manchester Children's Hospital**

Manchester

United Kingdom

-

**Study participating centre**

**The Royal London Hospital**

London  
United Kingdom

-

**Study participating centre**

**Bristol Royal Children's Hospital**

Bristol  
United Kingdom

-

**Study participating centre**

**UCL Great Ormond Street Institute of Child Health**

London  
United Kingdom

-

**Study participating centre**

**Faculty of Medicine, University of Southampton**

Southampton  
United Kingdom

-

**Study participating centre**

**Institute Of Life Course And Medical Sciences**

Liverpool  
United Kingdom

-

**Study participating centre**

**Royal Hospital for Sick Children**

Edinburgh  
United Kingdom

-

**Study participating centre**

**Nationwide Children's Hospital**

Columbus

United States of America

-

**Study participating centre**

**University of Utah School of Medicine**

Salt Lake City

United States of America

-

**Study participating centre**

**University of Tennessee Health Science Center**

Tennessee

United States of America

-

**Study participating centre**

**University of Chicago**

Chicago

United States of America

-

**Study participating centre**

**Children's Mercy Kansas City**

Kansas City

United States of America

-

**Study participating centre**

**University Teaching Hospital of Lusaka**

Lusaka

United States of America

-

**Sponsor information**

## Organisation

Foundation KiKa

## ROR

<https://ror.org/05gxzef39>

## Funder(s)

### Funder type

Other

### Funder Name

Investigator initiated and funded

## Results and Publications

### Individual participant data (IPD) sharing plan

Following publication of the study results, the full, anonymous de-identified patient dataset will be made available. Proposals should be directed to [sct-study@amsterdamumc.nl](mailto:sct-study@amsterdamumc.nl) to gain access. Data requestors will need to sign a data access agreement.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		06/09/2024	28/11/2024	Yes	No
<a href="#">Protocol file</a>			17/04/2024	No	No